PRE-INSPECTION SELF-ASSESSMENT CHECKLIST

MODERATE COMPLEXITY TESTING KITS

SPECIALTY:	Bacteriology	Direct Strep antigen
	General Immunology	Mononucleosis; Helicobacter pylori; Rheumatoid factor
	Endocrinology	Serum HCG (serum pregnancy test)

TEST COMPLEXITY:
These tests may be categorized as waived, moderate or high complexity testing, depending on the analyte and the specific test kit. Refer to a current Waived Test List (available from the LQA Office) to determine if a specific test system (exact name and manufacturer) is waived. Follow all manufacturer's instructions for performing the waived test.

If the specific test system (exact name and manufacturer) is not listed on the Waived Test List, it is moderate or high complexity. (Call the LQA Office for assistance or go to the Test Complexity List at www.phppo.cdc.gov/dls/clia/testcat.asp)

The following requirements apply to test kits of moderate complexity:

PROFICIENCY TESTING:
Required for all non-waived Strep antigen, Mono, RA and serum HCG kits. Must perform biannual verification of accuracy for all non-waived H. pylori kits.

PERSONNEL

___ The director, supervisor and testing personnel meet personnel qualifications for moderate complexity testing [42 CFR Part 493 subpart M (CLIA) - Available from the LQA Office]

___ Documentation of personnel education, experience, training for the testing performed

___ Annual documentation of the assessment of personnel competency

___ Training is provided to personnel when problems are identified

___ Laboratory safety policies are written and staff adhere to them

QUALITY CONTROL

___ Procedures are written including: specimen collection and handling, test performance; result interpretation; reporting protocol; quality control; quality assurance. (Product inserts may be used if all information is addressed)

___ Test kits and reagents are properly labeled, stored at the proper temperature and used within expiration date

___ Each new lot or shipment of testing kits are checked with external positive and negative controls and results are recorded

TESTING KITS CHECKLIST

___ If procedural controls are part of each patient test, the results of the procedural controls are documented each day of patient testing.

___ If procedural controls are <u>not</u> part of each patient test, positive and negative external controls are performed each day of patient testing

___ If titers are reported, a control with a known titer must be run each day of patient testing. (Acceptable agreement may be considered plus or minus one dilution)

QUALITY ASSURANCE

___ Policies are written and there is evidence of review of quality control, quality assurance, proficiency testing (or biannual verification) and patient test results

___ Policies are written regarding specimen acceptance/rejection

___ Policies are written defining critical values (as applicable)

___ Documentation of corrective actions when problems are identified

___ Assure that adequate space and facilities are available

___ Adhere to local, state and federal regulations for hazardous waste disposal

RECORDKEEPING

___ Patient test orders include: patient name or identifier; person ordering the test; date and time of specimen collection; patient age and sex (if appropriate)

___ Patient test reports include: name and address of where tests were performed; patient name or identifier; date specimen received; date reported; normal ranges; specimen limitations

___ Records are kept for 2 years of lot numbers and expiration dates of kits and dates when placed into use

___ The following records are maintained for 2 years: Requisitions; test records; reports; quality control; quality assurance; proficiency testing; and biannual verification of accuracy data

___ Temperature records of space where kits and other testing materials are stored (i.e., refrigerator and/or room temperatures)